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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/825,896 04/05/01 STEINER

J 23105-B

EXAMINER

HM12/0917

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ART UNIT

PAPER NUMBER

1614

DATE MAILED:

09/17/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
**09/828,896**

Applicant(s)  
**Steiner et al**

Examiner  
**Rebecca Cook**

Art Unit  
**1614**



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 6-8, 10-12, 14-16, 18-20, and 22-27 is/are pending in the application.
- 4a) Of the above, claim(s) 6-8, 10-12, 14-16, 18-20, and 22-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 25-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some\* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 3
- 18) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

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Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 6-8, 10-12, 14-16, 22-24, drawn to a method of use, classified in class 514, subclass 427, among others.
- II. Claims 25-27, drawn to a composition, classified in class 514, subclass 427, among others.

The inventions are distinct, each from the other because:

Inventions of Group II and Group I are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product can be used in a materially different process such as an immunosuppressive.

Because these inventions are distinct for the reasons given oabove and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

During a telephone conversation with Lee Heiman on 6/19/01 a provisional election was made with traverse to prosecute the invention of Group II, claims 25-27. Affirmation of this election must be made by applicant in replying to this Office action. Claims 6-8, 10-12, 14-16, 18-20, 22-24 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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To further prosecution applicants are requested to cancel the non-elected invention.

The drawings have been approved by the draftsman.

Claims 11-15 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

There is no support in the specification for substituting the ester or amide at any carbon in the heterocyclic compound. They are all substituted at the C-2 position.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for some of the compounds, does not reasonably provide enablement for rapamycin. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. To the extent that intended use of a composition is patentable CA122:230322 discloses that rapamycin does not initiate hair growth.

Claims 25-27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no antecedent basis in claim 25 for the recitation "a second hair revitalizing agent."

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A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claims 25-27 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 22-24 of prior U.S. Patent No. 6,239,164. This is a double patenting rejection.

Applicants are requested to identify applications in which there are conflicting claims and eliminate such claims from all but one application in the absence of good and sufficient reason for their retention during pendency in more than one application. See CFR 1.78(b). Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822. Applicants are also requested to identify any related cases in which there might be double patenting.

Steiner, CA 126:272710; Blaschke et al, 1974, CA85:78405k; Nicolaou et al, Am. Chem. Soc., 1993; Nicolaou et al, Che. Eur. J., 1995; Shu et al, J. Labelled Comp. Radiopharm., 1996; Smith, et al, J. Am. Chem. Soc., 1995; Soai et al, J. Chem. Soc. 1982; Waldmann, Synlett, 1990; Waldmann, Liebigs Ann. Chem, 1991; and Wasserman et al, J. Org. Chem., 54(22), 1989 could not be considered. They were not received.


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The foreign language references were considered to the extent of their English language abstracts or their formulas.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Cook whose telephone number is (703) 308-4724. The examiner can normally be reached on Monday through Friday from 6:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marianne Seidel, can be reached on (703) 308-4725. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

  
REBECCA COOK  
PRIMARY EXAMINER  
GROUP 1200

September 11, 2001